

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments in the following remarks.

**I. CLAIMS STATUS OF AMENDMENTS**

Claims 1-12 were examined on the merits and stand rejected.

Claims 1-12 have been amended to make minor editorial revisions thereto to better conform to U.S. claim form practice. Such revisions are non-substantive and not intended to narrow the scope of protection. Such revisions include: replacing the "characterized by" language with "wherein" language; revising the beginning of the claims to recite "a" or "the"; revising the claim language throughout to provide proper antecedent basis for the recited claim terminology; and revising the claims to remove redundant and unnecessary language, including reference numerals to Figures. Support can be found throughout the disclosure and the original claims.

New independent claims 13 and 14 have been added. Support for the new claims can be found in original claims 1 and 8 and in the disclosure, for example, at page 2, lines 10-33, and page 4, lines 1-25.

No new matter has been added by the above claim amendments.

Claims 1-14 are pending upon entry of this amendment.

The specification is amended to include appropriate section headings to conform to U.S. practice. No new matter has been added.

Applicants are submitting the present amendment without prejudice to the subsequent prosecution of claims to some or all of the subject matter which might be disclaimed by virtue of this response (although none is believed to be), and explicitly reserve the right to pursue some or all of the subject matter, in a divisional or continuation applications.

Applicants thank the Examiner for the careful examination of this case and respectfully request reconsideration of the case as amended. Below Applicants address the rejections in the Office Action and explain why the rejections are not applicable to the pending claims as amended.

## **II. INFORMATION DISCLOSURE STATEMENT**

The Office did not consider EP0923908, EP0786235, and WO94/10928 in the Information Disclosure Statement of December 22, 2005, on the basis that Applicants did not provide copies of these documents to the Office. See item 2 on page 2 of the Office Action.

Applicants respectfully submit that the references should have been officially considered by the Office, because copies of the references were forwarded to the USPTO from the international search authority pursuant to the trilevel agreement

between the USPTO, EPO and JPO. Thus, the references should have been considered as they should be of record at the USPTO. Further, Applicants note that an English language version of the international search report, citing these references, was submitted with the December 22, 2005 IDS. For the reasons, it is believed that the references should have been considered. Therefore, kindly consider the noted references in the December 22, 2005 IDS, and return an Examined-initialed copy of the PTO 1449 Form indicating such.

### **III. OBJECTION TO THE SPECIFICATION**

In items 3-4 on page 2 of the Office Action, the specification was objected to for containing a minor informality with respect to a spelling error.

It is believed that the present amendment overcomes this objection by appropriately amending the specification to correct the noted spelling error. Therefore, the objection is untenable and should be withdrawn.

### **IV. INDEFINITENESS REJECTIONS**

Claims 1-12 were rejected in the 35 U.S.C. § 112, second paragraph, as being indefinite for the reason set forth in items 6-9 on page 3 of the Office Action.

This rejection is respectfully traversed.

Applicants have amended the claims to better define the subject matter more clearly and distinctively in a non-narrowing manner. Specifically, in reply to item 7, claim 1 has been amended to remove the "such as" language and to positively recite the limitations in the claim.

In reply to item 8, the claims have been amended to provide proper antecedent basis for the limitations "flexible structure" in claims 5 and 10-12.

In reply to item 9, Applicants have amended the claims to better to conform to U.S. claim form of practice and to correct the grammatical and idiomatic errors therein.

The claims are thus clear, definite and have full antecedent basis.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

#### **V. OBVIOUSNESS REJECTIONS**

Claims 1-4, 8 and 9 were rejected under 35 U.S.C. § 103(a) as being obvious over TAYLOR et al. (US 6,267,765), in view of ASNIS et al. (US 5,217,462) for the reasons set forth in item 13 on pages 4-7 of the Office Action.

Claims 5-7 and 10-12 were rejected under 35 U.S.C. § 103(a) as being obvious over TAYLOR and ASNIS and further in view of BEYAR (US 2002/0095181) for the reasons set forth in item 14 on pages 7-8 of the Office Action.

These rejections are respectfully traversed and will be discussed together below. It is noted that TAYLOR and ASNIS are used as the primary and first secondary reference in the rejections.

It is well established that to support a *prima facie* case of obviousness, the Office must provide a rationale showing that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions to yield predictable results. KSR International CO. V. Teleflex Inc., 550 U.S. \_\_\_, \_\_\_, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385, 1395 (2007); and M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2143.02.

A usual vertebral osteosynthesis device comprises extension pieces engaged on the proximal studs of the anchoring members that do not allow introducing the clamping nuts simultaneously with the connecting parts.

By contrast, the invention of independent claims 1, 13, and 14 provide a device in which the extension pieces are sized to allow the introduction of the clamping nuts thereon. The extension pieces are positioned by positioning member enabling to position the extension pieces on the free ends of the proximal studs. The invention brings considerable advantages, indicated in the disclosure.

It should be noted that said extension pieces are used only at the moment of the implantation of the device, and are not pieces intended to be implanted.

These features are reflected in independent claim 1, which recites: "one or more extension pieces adapted for engaging said proximal threaded studs of the bony anchoring members for running down connecting parts on said proximal threaded studs so that said extension pieces rest on a proximal zone of a base portion of the bony anchoring members; wherein the proximal threaded stud of at least one anchoring member and the corresponding extension piece used with said bony anchoring member include a positioning member adapted to position the extension piece concentrically on a free end of the proximal threaded stud, said positioning means being such that the extension piece comprises an end distal portion having an external diameter adapted to let through the nut thereon."

Neither TAYLOR, nor ASNIS, nor BEYAR, nor any combination thereof discloses or suggests this feature.

TAYLOR discloses an implanted device (polyaxial vertebral screw with proximal stud, linking rod, connecting part, clamping nut). The Examiner states that it would have been obvious to construct the stud in various elements when an integral stud is known by the cited prior documents. Applicants respectfully disagree.

In this regard, TAYLOR does not disclose at all an extension piece but only various kinds of implantable devices.

TAYLOR in no way suggests the invention of independent claim 1. On the contrary, TAYLOR diverts the skilled artisan away from the claimed invention. In this regard, in the polyaxial screw according to TAYLOR, the proximal end of the stud comprises a half-circle shaped proximal end for immobilizing the stud in rotation when screwing the nut. This proximal end has the same width than the diameter of the stud. Accordingly it would be impossible to connect thereon an extension piece having a diameter not bigger than the diameter of the stud, so as to allow the nut to be introduced along the extension piece and then on the stud. See the end of claim 1 and new claims 13 and 14.

This stands in contrast to the arrangement of claim 1. See the end of claim 1, which recites: "said positioning member being such that the extension piece comprises an end distal portion having an external diameter adapted to let through the nut thereon." See also, the end of claim 13, which recites: "said positioning member being such that said extension piece comprises an end distal portion having an external diameter that is smaller than a diameter of the corresponding proximal threaded stud to thereby allow introduction of the nut along said extension piece." See also, the end of claim 14, which recites: "said positioning member being such that said extension piece comprises an end distal portion having an external diameter that is smaller

than a diameter of the corresponding proximal threaded stud to thereby allow introduction of the nut along said extension piece."

Therefore, TAYLOR fails to disclose or suggest each and every element of claims 1, 13 and 14, and thus, it cannot be considered as a basic document on which said person of the art could find a large part of the solution to the technical problem, or on the basis of which this person would be encouraged to modify the existing device.

ASNIS fails to remedy the deficiencies of TAYLOR. ASNIS describes a two-part screw used to make a compression of fractured bone parts.

This screw is composed of two parts and is intended to be implanted (and not with a non-implanted part intended) at the moment of the implantation, to be temporarily connected to an implanted part to introduce other implanted parts on said implanted part. Therefore, there is no implantation of a first part in a first time and of the second part in a second time, but the two parts are implanted simultaneously.

Furthermore, no other implanted parts are to be introduced on the distal part, and the proximal part has an enlarged head which prevents any introduction of a nut on it, intended to be screwed on the distal part. Anyway, no nut is intended to be screwed on this distal part, this distal part being intended to be completely screwed in the bone. Finally,



the diameter of the proximal part is bigger than the diameter of the threaded portion of the distal part, which is the strict opposite of the main feature of claims 1, 13, and 14, wherein the diameter of the extension part is smaller than the diameter of the threaded portion of the stud, so as to allow the introduction of a nut along the extension part, which nut is intended to be screwed on the stud. See again, the end of claims 1, 13 and 14.

Thus, the cited prior art documents lack a teaching or suggestion of an extension part used to introduce nuts along it, which nuts are intended to be screwed on a distal part previously implanted. There is also rationale for modifying the teachings of these references to arrive at the claimed device.

For these reasons, claims 1, 13 and 14 are novel and nonobvious over the cited references.

Claims 2-12 depend on claim 1. Therefore, these dependent claims are also novel and nonobvious over the cited references for the same reasons in view of their dependency on claim 1.

It is believed that the rejections fail in view of the discussion of TAYLOR and ASNIS. Therefore, there is no need to discuss the secondary reference of BEYAR.

In view of the above, Applicants respectfully submit that neither TAYLOR, nor ASNIS, nor BEYAR, nor any combination thereof, disclose or suggest each and every element of claims 1, 13, and 14.

Thus, the above noted 103(a) obviousness rejections are untenable and should be withdrawn period.

#### VI. CONCLUSION

Having addressed all the outstanding issues, the amendment is believed to be fully responsive. In view of the above, it is respectfully submitted that the application is condition for allowance and notice of the effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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